

DRAFT



**DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420**

**IL 12-2004-
In Reply Refer To:12**

June XX, 2004

HEALTH SERVICES RESEARCH AND DEVELOPMENT SERVICE

**SOLICITATION OF APPLICATIONS FOR
DEPLOYMENT HEALTH SERVICES RESEARCH**

1. Purpose.

The Veterans Health Administration (VHA) is expanding its focus on meeting the needs of veterans returning from deployment. Designated research funds are available to support research focused on *deployment health care needs and services*. The VHA is charged to care for veterans and the men and women who serve in our armed forces. The Health Services Research and Development Service (HSR&D), Office of Research and Development (ORD), Department of Veterans Affairs (VA) is exploring three major categories related to deployment health as priorities:

- Health delivery system organization resources, structures and processes of utilization of a continuum of health services
- Population characteristics, and
- Health and satisfaction outcomes

2. Background.

A *deployment health care need* is defined as a person's health concern about an event or activity related to duty in the Nation's armed forces that involves a military operation, location, command, or exposure to combat and other hazardous environments. Deployment health care need may also apply to individuals who were not deployed (e.g. family members or informal caregivers), but have health concerns that relate to a veteran's deployment. Specific war-related conditions include, but are not limited to: musculoskeletal system, digestive system, nervous system, and mental disorders; unexplained illness, fibromyalgia and chronic fatigue, military sexual trauma, ionizing radiation, Gulf War Syndrome, Post Traumatic Stress Disorder (PTSD), Amyotrophic Lateral Sclerosis (ALS), Anthrax reactions, Malaria, Tuberculosis (TB), Leishmaniasis, depleted uranium, traumatic amputation, spinal cord injury and other injuries.

Service members face potentially hazardous environments with increasing frequency, due to more frequent deployments and downsizing of the active-duty armed forces since the end of the Cold War. It is therefore imperative that the HSR&D Service fill gaps in knowledge and practice by expanding its research program on deployment health. The results of this research program will support the evidence-based delivery of high quality, cost-effective health care for veterans of all deployments and the men and women who serve in our armed forces.

3. Scope of HSR&D Research Interests.

VA is one of the largest national health care systems and supports a natural collaborative relationship with the military. As all federal agencies move toward increased coordination, preparedness and response capabilities, an important goal of this solicitation is to prepare VHA organizations for change, to transform the VISNs into learning organizations that can efficiently implement evidence-based practices for deployment health concerns. Collaborations with military health care organizations and other ORD research services are intended to help improve clinical service provision to veterans locally and within VISNs and provide lessons learned for expanding successful organizational changes nationwide.

HSR&D calls upon its investigators to build on previous efforts by VA, DOD and HHS, by identifying gaps and quickly applying evidence to optimize impacts on system improvements and patient health outcomes. Studies that capitalize on this growing body of knowledge will provide key guidance to VA leaders as they both move the organization into an enhanced state of preparedness and collaborate with the national deployment health agenda. Investigators are also advised to develop projects that will expand other funded work of HSR&D investigators and relevant research funded outside VA. Additional scope and background material may be found in Appendix A.

4. Examples of Research Issues.

The HSR&D Service will support a broad spectrum of research that focuses on measuring effectiveness within the areas listed below. Examples of research interests for HSR&D include:

Population characteristics

HSR&D is interested in studies related to predisposing, enabling and need characteristics of the post-deployed population and informal caregivers and family members. Poorly understood deployment syndromes have been a recurring concern since the time of the Civil War. Post deployment health concerns may be poorly understood but can be systematically evaluated and diagnosed. Medically unexplained symptoms may precede identification of whole new diagnostic entities (e.g. chronic fatigue syndrome). Research questions may include:

- a) Describe social support systems, positive and negative health behaviors, socio-economic factors, rank and rate of military role, family and living conditions.
- b) Describe deployment concerns related to family members and informal caregivers.
What educational and training needs exist for caregivers who will provide for care

coordination, hands-on care provision, feeding and other care in the home or alternative settings.

- c) Women veterans of recent conflicts have presented with a wide range of physical and psychological conditions. Why have a higher percentage of separated female Iraqi Freedom veterans sought health care from VA than female Enduring Freedom veterans? How do female and male deployment health concerns differ? For example, is the definition of PTSD appropriate to the combat trauma responses of both females and males? Develop, implement and evaluate delivery systems to address women veteran's health issues (e.g. military sexual trauma).
- d) National Guard and Reserve members of combat forces represent the largest proportion of Iraqi and Enduring Freedom forces presenting for VA health care services. Do family separation, social support, and coping issues vary across National Guard, Reserve, and Active Duty forces? How do the cultures of these different armed forces differ?

Health delivery system organization resources, structures and processes

HSR&D is interested in studies relevant to organizational structures, cultural environments, processes and provider behavior related to coordinating care and reducing disruptions in care for returning war veterans, both internally and also in coordination with DOD. Studies intended to explain and provide guidance for improvements in the design, administration or management of deployment health concerns are desired, including system-level integration and transition planning, outcomes, quality of care, cost, cost-effectiveness, access to needed services and efficient provision of services. The shift in health care delivery from hospital to ambulatory care settings has resulted in patient family members playing important roles in patient care and decision-making. Patients often rely on family caregivers to meet treatment needs, assist with care, provide emotional support and coordinate health delivery system access. Often family members may not be prepared to meet these patient needs. Therefore, studies with this population are welcome.

Research issues may include, but are not limited to:

- a) Study the organizational factors that promote accurate and timely surveillance, case finding and early response to deployment health concerns. Conduct case studies on how VA managers have effectively (or ineffectively) responded. Implement and evaluate systems among Patient Care Services, Office of Quality and Performance and the Office of Research and Development to provide coordinated care and quality outcomes in deployment health concerns. Design and test interventions to facilitate the coordination of care and transition across health care settings for post-deployment veterans.
- b) Explore the influence of clinical tools, such as clinical practice guidelines, on communication regarding deployment health concerns and in patient and family assessment, treatment and outcomes.
- c) Test algorithms that alert providers to acute risks and help identify deployment health concerns as early as possible. Determine VA system-wide barriers and facilitating factors that promote early identification, treatment, and prevention capabilities.

- d) Explore the influence of telemedicine systems on organizational structures, clinical processes and management procedures. Implement and evaluate information and decision support systems to provide appropriate self-care information for the recently deployed population and their informal caregivers and family members. Explore the usefulness and relevance of Health-e-vet to the newest generation of computer-savvy recently-deployed veterans and men and women of the armed forces.
- e) Test databases, systems and procedures that link epidemiological, environmental and clinical surveillance systems and/or databases such that suspected exposures and cases are identified early. Test the sensitivity and predictive value of using routine systems and processes, then test feedback mechanisms that promote on-going communication from these systems throughout the VA system.
- f) Implement and evaluate multidisciplinary care teams to provide appropriate deployment health primary care services.
- g) Develop, implement and evaluate organizational supports for informal caregivers or family members who will negotiate the health care system, provide hands-on care and maintenance, and medication or other treatments of the veteran in the home or other setting.
- h) Test the validity and reliability of instruments and measures previously designed for use with older adults and prior deployment exposures. For example, is the SF 36-V valid and reliable in the newest post-deployed population?
- i) Evaluate the implementation of systems for the application for VA benefits and subsequent smooth transition of armed services members' with deployment health concerns from the Department of Defense health care system to the Veterans Affairs health care system.
- j) Explore the utilization of services along the continuum (e.g. outpatient, in-patient hospitalization, emergency room, nursing home, home care, pharmacy) for those with deployment health concerns. Are there differences in utilization for those with medically unexplained symptoms versus other deployment health concerns?
- k) What health delivery system level, provider level and patient level organizational systems and processes have been developed and are effective for supporting family caregiver interventions? What support needs exist for family caregivers and veteran patients?
- l) Develop, implement and evaluate improved prevention, screening, and management techniques and tools for illnesses that are often deployment-related (e.g. PTSD).
- m) Design and evaluate interventions to support family caregivers or family systems involved in the care of post-deployment veterans' illnesses or injuries.

Health and satisfaction outcomes

The impact of interventions on intermediate and long - term health and functional status of veterans and family caregivers as well as the satisfaction levels of formal and informal caregivers and veterans is of interest to health services research. Additional outcomes of interest include but are not limited to cost effectiveness analysis, cost utility analysis, and quality of well-being.

- a) What is the impact of clinical practice guideline implementation on veterans' health outcomes and satisfaction with care?

- b) What is the impact of care coordination and education systems implemented to assist and educate informal caregivers and family members in the care and support of veterans with deployment health concerns?
- c) Development of measures and mixed quantitative and qualitative research methods for assessing patient factors that influence the outcomes of healthcare services are needed. Explore patient perceptions and values related to their condition and its treatment and management, patient decision making, provider decision making, and behavior. For example, measures and methods to assess patient treatment goals and preferences, patient satisfaction with prescribed regimens and screening and identification of patients with deployment health concerns. Are existing measures and methods appropriate, valid and reliable for the newest generation of combat veterans?
- d) Development, evaluation and determination of the effectiveness and outcomes of new interventions for PTSD.
- e) Evaluate outcomes while taking into account important contextual variables, such as military culture, family and other social support systems, role conflicts and changes, characteristics of the work environment, differences in treatment success associated with gender or other equity concerns.
- f) Explore the impacts of interventions and processes on outcomes for veterans, family caregivers, and clinical providers.

5. General Information

Proposed projects are expected to employ state-of-the-art research methods appropriate to the research question and population studied. In general, priority will be given to explanatory and outcomes studies as opposed to basic descriptive studies. It is expected that most studies will require collection of primary data, possibly in combination with secondary data.

Research proposals will be reviewed for scientific merit, relevance to the veteran population, capability of applicant to meet intended outcome of proposed research program, and potential contribution of proposed research to the field of deployment health, health services research and ultimately quality of life to veterans. Criteria for evaluation and review are:

- a) Relevance to veteran population
- b) Relevance of stated hypothesis to the VA HSR&D mission
- c) Relationship of stated hypothesis to proposed research activities and/or methodologies
- d) Potential of proposed research plan to produce new and beneficial information with the expectation for therapeutic intervention and exponential increase in research findings
- e) Incorporation of expertise required to carry out all facets of the proposed research plan,
- f) Contribution to overall VA research portfolio
- g) Appropriateness (in qualitative study methods) and / or statistical significance (in quantitative study methods) of VA patient pool

- h) Adequacy of VA facilities and equipment
- i) Ability of budget to cover all reasonable costs related to the proposal, and
- j) Appropriateness and detail of subcontract (if required).

Funding of proposals is contingent upon the availability of funds.

Important Due Dates:

- | | |
|----------------------------|------------------------|
| a) Letters of Intent: | October 15, 2004 |
| b) Proposals: | December 15, 2004 |
| c) Review: | March 13, 14, 15, 2005 |
| d) Projected Funding Date: | July, 2005 |

See Appendix C for requirements.

Applications and instructions for the HSR&D standard review process are available on the website at <http://www.vard.org>. All applications should follow the HSR&D process. Direct questions about scientific and/or research issues concerning this solicitation for proposals to: Christine Elnitsky, Ph.D., Assistant Director for Research Methodology for HSR&D Service, at 202-254-0199 or Christine.elnitsky@hq.med.va.gov.

Christine Elnitsky, PhD
Assistant Director for Research Methodology
Health Services Research and Development Service (124M)
810 Vermont Ave. N.W.
Washington, D.C. 20420

Jonathan B. Perlin, MD, PhD, MSHA, FACP
Acting Chief Research and Development Officer

Attachments

DISTRIBUTION:

CO: E-mail
FLD: VISN, MA, DO, OC, OCRO, and 200-E-mail

APPENDIX A BACKGROUND and SCOPE

BACKGROUND INFORMATION

Deployment missions vary and may include peacekeeping, humanitarian assistance, joint force exercises, construction projects, refugee relief, low intensity conflict, and war. During the past decade, U.S. armed forces have been deployed to overseas operations, other than war, more frequently than ever before. At the same time, National Guard members have been deployed within the U.S. to conduct operations such as assisting with counter-terrorism initiatives, fighting forest fires, providing disaster relief, and supporting border patrol and drug interdiction efforts.

The war on terror has produced a new generation of armed forces members and veterans who are at increased risk of medical and psychological illnesses due to deployment related exposures. By April 2004, in excess of 175,000 troops had served, more than 2,100 troops had been wounded by hostile fire and approximately 400 troops from Iraq had been medically evacuated for deployment/mental health problems. Reserve and National Guard members have participated in these deployments.

Military and veteran health care delivery systems, service and access dimensions differ. Barriers to enrollment, access and coordination of care exist as service members are transferred from military delivery system to veteran delivery system. Military health systems include active duty military providers and contractors. VA Medical Centers include civilian providers who may have no military service experience. The cultures of these two provider populations vary. The new generation of veterans presents special needs in terms of resources, staffing and training of VA provider populations. VA aims to coordinate care and reduce disruptions in care for returning war veterans.

SCOPE of INTEREST INFORMATION

In accordance with Public Law 105-368, VA established two War Related Illness and Injury Study Centers (WRIISCs) to respond to health concerns of veterans from past and future exposures and conflicts. The centers are located at the VA New Jersey Health Care System, East Orange Campus and the VA Medical Center, Washington, D.C. WRIISCs apply scientifically rigorous models of care, research and education to war-related illnesses and post deployment health concerns.

VA currently funds research projects that are related to military occupational and environmental exposures. For example, the Rehabilitation Research and Development Service (RR&D) is collaborating with HSR&D in a solicitation of applications for amputation and prosthetics outcomes research. An HSR&D program announcement invites research on terrorism: studies relevant to preparation for and response to nuclear, chemical, biological or explosive attacks. The Office of Research and Development (ORD) also has a program announcement for deployment health research. These announcements are listed in Appendix B.

The Institute of Medicine (IOM, 2001; IOM, 1998) recommends that veterans who experience deployment health concerns receive evaluation, follow-up and management in primary care settings to increase continuity of care and to establish ongoing therapeutic relationships. VA and Department of Defense (DOD), therefore, jointly developed an evidence-based post-deployment health evaluation program focused in the primary care setting. This clinical practice guideline (CPG) for the evaluation and management of post-deployment health concerns aims to improve patient outcomes by ensuring timely access to clinicians who are familiar with the unique health problems associated with deployment (VHA, 2001). As the CPG notes, “military members may experience physical or psychological trauma resulting from a variety of factors, such as combat, environmental extremes, illness or infectious disease, injury, weapons of mass destruction, and potential environmental threats. Deployment may create or exacerbate existing family problems and strain already fragile family relationships and coping mechanisms”. The objectives of the CPG are to: achieve satisfaction and positive attitudes regarding post-deployment medical care; identify and support decision-making for elements of care essential to all post-deployment evaluations; support patient education and communication; optimize data collection; focus on prevention in subsequent deployments; and provide a tool to support provider education.

In addition, VHA is implementing a new National clinical reminder system for post-deployment health screening to standard clinical evaluation reminder systems (see VHA Directive 2004-015). A national reminder, designed to detect some symptoms commonly identified in returning veterans has been released (see VHA IL 10-2004-001). Reminders target assessment of PTSD, Depression, Infectious Disease, and “Chronic Symptoms” and pain.

APPENDIX B
GENERAL REFERENCES RELATED TO RESEARCH NEEDS ON DEPLOYMENT
HEALTH SERVICES RESEARCH

1. General:

Department of Veterans Affairs: Strategic Plan for Employees 2003-2008. Office of the Secretary. Washington, D.C. (December 2003).

Department of Veterans Affairs: VA War Related Illness and Injury Study Centers (WRIISCs) Specialized Health Care, Research, Education and Outreach for combat Veterans with Difficult to Diagnose Conditions. Accessible at:
<http://www.va.gov/environagents>.

Hyams KC, Wignall FS, Roswell R. (1996) War syndromes and their evaluation: from Civil War to Gulf War. Annals of Internal Medicine 125 (5) 398-405.

Institute of Medicine (2001). Gulf War Veterans: Treating Symptoms and Syndromes. Washington D.C.: National Academy Press.

Institute of Medicine, Committee on the Evaluation of the Department of Veteran Affairs Uniform Case Assessment Protocol (1998). Adequacy of the VA Persian Gulf Registry and Uniform Case Assessment Protocol. Washington, DC.: National Academy Press.

Senge, PM, et al., (1999) The Dance of Change: the Challenges of Sustaining Momentum in Learning Organizations. New York: Doubleday.

Senge, PM (1994). The fifth Discipline Fieldbook: Strategies and Tools for Building a Learning Organization. New York: Currency.

Tomsho, R. (September 11, 2003) Veterans Affairs Alters Procedures for Injured Troops. Wall Street Journal article accessed on-line.

Martin, D. (December 4, 2003) The Long Road Home. 60 Minutes II. Accessed at <http://www.cbsnews.com/stories/2003/12/01/60II/main586138.shtml>

CBS Broadcasting Inc/ Associated Press. (January 14, 2004) Iraq Troops Suicide Rate Spikes. Accessed at <http://www.cbsnews.com/stories/2004/01/14/iraq/main593160.shtml>

Veterans Health Administration (Feb. 2001). Post Deployment Evaluation and Management. Office of Quality and Performance and the Veterans Affairs and Department of Defense Development Work Group. OQP publication 10Q-CPG/PDH-01. Washington, D.C.: Veterans Health Administration, Department of Veterans Affairs.

2. Program Announcements and Solicitations :

ORD Program Announcement on Deployment Health Research. Accessed at <http://www1.va.gov/resdev/fr/ProgramAnnouncementDeploymentHealthIssues.pdf>

ORD solicitation for Applications For Amputations and Prosthetics Outcomes Research. Accessed at http://www.hsrd.research.va.gov/for_researchers/funding/solicitations/ORD-amputation-RFP-3_16_04.pdf

HSR&D Program Announcement Inviting Research On: Terrorism: HSR&D Studies Relevant to Preparation for and Response to Nuclear, Biological, Chemical or Explosive Attacks. Accessed at http://www.hsrd.research.va.gov/for_researchers/funding/solicitations/TerrorismSolicitation1-30-02.pdf

HSR&D Targeted Research Announcement. VISN/HSR&D Implementation Collaborative: Innovations to Implement Evidence-Based Clinical Practice. <http://www.appc1.va.gov/resdev/fr/frrfp/implementation.pdf>

3. Related Web Sites:

Deployment Health Clinical Center
<http://www.deploymenthealth.mil/research/default.asp>

Undersecretary for Health Information Letter, February 6, 2004.
http://www.va.gov/vdl/VistA_Lib/Clinical/CPRS-Clinical_Reminders/PWRM_1_5_21_SETUP.doc

War Related Illness and Injury Study Center, VAMC Washington, D.C.
www.va.gov/WRIISC-DC

War Related Illness and Injury Study Center, VA New Jersey Health Care System East Orange, N.J.
www.wri.med.va.gov

DOD Center for Deployment Health Research at the Naval Health Research Center
<http://www.nhrc.navy.mil/rsch/code25/program5.htm>

APPENDIX C REQUIREMENTS

1. Proposals must incorporate proven techniques for adequate analysis and dissemination of results in leading peer-reviewed journals. Therefore proposals must:
 - a. Use adequate subject pools,
 - b. Incorporate rigorous quantitative statistical analyses or qualitative analysis, and
 - c. Clearly define and assess outcomes.
2. Although preliminary data in support of the studies is not required, a demonstration of previous research, sound rationale, and appropriate expertise is expected.
3. Principal investigator (PI) and co-principal investigators (Co-PIs) must have Ph.D. and/or M.D. degrees and at least a 5/8th Department of Veterans Affairs (VA) appointment.
4. All applicants must submit a Letter of Intent (LOI) that is received in VA Central Office (124M) by October 15, 2004. LOIs must be directed through the Associate Chief of Staff for Research and Development (ACOS/R&D) and include:
 - a. Names of key investigators (PI, Co-PI, co-investigators),
 - b. Brief background,
 - c. Clearly stated hypothesis,
 - d. Outline of Methods,
 - e. Estimated Budget, and
 - f. Appropriate references.
5. This Request for Proposals will be funded by Program Funding (824). The applicant must be solely responsible for planning, directing, and executing the proposed project. The applicant may request up to \$250,000 direct costs per year for 3 years.
6. Proposals received in response to this announcement will undergo merit review, by the HSR&D Scientific Merit Review Boards (SMRBs). The review is rigorous and standards are very high; both scientific merit and expected contribution to improving VA health services are considered.